



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0627]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in existing FDA regulations regarding the general administrative procedures for a person to petition the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a rule; to file a petition for an administrative reconsideration or an administrative stay of action; and to request an advisory opinion from the Commissioner.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions--(OMB Control Number 0910-0183)--Extension

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule.

Section 10.30 (21 CFR 10.30) sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20) (submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions, or groups.

Section 10.33 (21 CFR 10.33) issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under 21 CFR 10.25 (initiation of administrative proceedings). A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a

petition no later than 30 days after the decision involved. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting from the Commissioner of FDA a reconsideration of a matter.

Section 10.35 (21 CFR 10.35), issued under section 701(a) of the FD&C Act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to Division of Dockets Management), the Commissioner to stay the effective date of any administrative action.

Such a petition must do the following: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the FD&C Act sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to Division of Dockets Management), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the

formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the Agency's formal position for matters of general applicability.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|----------------|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 10.30 | 207 | 1 | 207 | 24 | 4,968 |
| 10.33 | 4 | 1 | 4 | 10 | 40 |
| 10.35 | 5 | 1 | 5 | 10 | 50 |
| 10.85 | 4 | 1 | 4 | 16 | 64 |
| Total | | | | | 5,122 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates for this collection of information are based on Agency records.

On December 19, 2013, FDA published a technical amendment (78 FR 76748) announcing that the Agency is modernizing its administrative regulations regarding submission of citizen petitions to explicitly provide for electronic submission. The current regulation does not recognize electronic methods for submitting citizen petitions; thus, this action will enable efficiency and ease in the filing of citizen petitions.

The Agency still allows for non-electronic submissions, however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and straightforward approach. FDA has created a single docket on <http://www.regulations.gov>, the U.S. Government's consolidated docket Web site for Federal Agencies, for the initial electronic submission of all citizen petitions. The FDA Electronic Method for Submission of Citizen Petitions Docket, Docket No. FDA 2013-S-0610, allows the petitioner to create an electronic submission through <http://www.regulations.gov> and provides an alternative to the current system

of submission for citizen petitions.

Electronic submissions through <http://www.regulations.gov> will provide the submitter with an immediate record of the time of submission. FDA's Division of Dockets Management (DDM) (<http://www.fda.gov/RegulatoryInformation/Dockets/default.htm>) will continue to inform the submitter of formal filing; however, tracking will be more easily accomplished through electronic submission.

DDM will receive the electronically submitted citizen petition through the Federal Dockets Management System, the Agency component of <http://www.regulations.gov>. Subsequently, DDM will review the electronic submission and when it accepts the citizen petition for filing, DDM will assign a docket number to that petition, different from the FDA electronic submission docket number. This unique docket number from DDM identifies the docket for that particular citizen petition for all future filings and submissions related only to that citizen petition. Subsequent submissions associated with that citizen petition will refer to the assigned unique docket number. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA, and easier access to FDA to seek input through the citizen petition process.

Dated: March 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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